



## **CONSUMER PRODUCT SAFETY COMMISSION**

### **16 CFR Parts 1107 and 1112**

**[Docket No. CPSC-2021-0013]**

#### **Testing and Labeling Pertaining to Product Certification; Requirements Pertaining to Third Party Conformity Assessment Bodies**

**AGENCY:** Consumer Product Safety Commission (CPSC).

**ACTION:** Direct final rule.

**SUMMARY:** This direct final rule updates the testing and third party conformity assessment body rules to incorporate by reference current versions of ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E).

**DATES:** The rule is effective on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], unless CPSC receives a significant adverse comment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If CPSC receives such a comment, it will publish a document in the *Federal Register*, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You can submit comments, identified by Docket No. CPSC-2021-0013, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (e-mail), except through <https://www.regulations.gov> and as described below. CPSC

encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Mail/hand delivery/courier Written Submissions:* Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. Alternatively, as a temporary option during the COVID-19 pandemic, you may email such submissions to: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

*Instructions:* All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

*Docket:* For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC-2021-0013, into the “Search” box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Scott Heh, Program Manager, Third Party Laboratory Accreditation, U.S. Consumer Product Safety Commission, National Product Testing and Evaluation Center, Five Research Place, Rockville, MD 20850; 301-504-7646; email: [sheh@cpsc.gov](mailto:sheh@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Background**

Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires manufacturers and importers of children’s products to certify that their products comply with all applicable children’s product safety rules. Certification must be

based on third party testing by a CPSC-accepted laboratory. Section 14(a)(3) of the CPSA requires the CPSC to publish a notice of requirements for the accreditation of third party testing laboratories to determine whether a children's product conforms to the applicable children's product safety rule. CPSC promulgated regulations implementing these statutory requirements as described below.

*16 CFR Part 1107*

The CPSC regulation for testing and labeling is 16 CFR part 1107. The Commission promulgated the final rule in November 2011. 76 FR 69482. The regulation at 16 CFR part 1107, among other things, incorporated by reference International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard ISO/IEC 17025:2005(E), "General Requirements for the Competence of Testing and Calibration Laboratories" (ISO/IEC 17025) and ISO/IEC 17011:2004(E) "Conformity assessment – General requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies" (ISO/IEC 17011) in §1107.21 regarding periodic testing. All manufacturers of children's products must conduct periodic testing. All periodic testing must be conducted by a CPSC-accepted third party conformity assessment body.

Under part 1107 a manufacturer must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a year. The rule allows manufacturers to extend the time between required periodic testing to either two or three years, as follows:

- Two years – Required periodic testing by third party conformity assessment body may be extended to two years if the manufacturer

implements a production testing plan as described in 16 CFR

1107.21(c)(2).

- Three years – Required periodic testing by a third party conformity assessment body may be extended to three years for manufacturers conducting testing to ensure continued compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005(E). The testing laboratory used to ensure continued compliance during the three-year period is not required to be a CPSC-accepted testing laboratory. However, any ISO/IEC 17025:2005(E)-accredited testing laboratory used for ensuring continued compliance must be accredited by an accreditation body that is accredited to ISO/IEC 17011:2004(E) 16 CFR 1107.21(d)(1)).

Both ISO/IEC 17025:2005(E) and ISO/IEC 17011:2004(E) were incorporated by reference in the periodic testing section (§ 1107.21) of part 1107.

#### *16 CFR Part 1112*

The CPSC regulation for acceptance of third-party testing laboratories is 16 CFR part 1112. The Commission promulgated the final rule in March 2013. 78 FR 15836. The regulation at 16 CFR part 1112, among other things, establishes the baseline requirement for a laboratory to be CPSC accepted to conduct required third party testing on children's products. In order for a testing laboratory to be considered CPSC accepted, it must, among other things, be accredited to ISO/IEC 17025:2005(E), "General Requirements for the Competence of Testing and Calibration Laboratories" (ISO/IEC 17025). The testing laboratory's accreditation body must be a signatory to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA). Testing laboratories that are ISO/IEC 17025 accredited are

assessed to have the technical and managerial competence to conduct testing in accordance with the standards and test methods that are listed in the laboratory's scope of accreditation. The accreditation body issues the accreditation scope for the laboratory and posts it for public viewing on the accreditation body's website. When the final rule was promulgated, ISO/IEC 17025:2005(E) was incorporated by reference in part 1112 (§ 1112.13).

## **B. Revisions to the ISO/IEC Standards**

In 2017, ISO/IEC published updated versions of ISO/IEC 17025 and ISO/IEC 17011. A general description of the standards and what changes were made in the revisions follows.

### *Scope and Purpose of ISO/IEC 17025*

Testing laboratories that are accredited to ISO/IEC 17025 have demonstrated that they operate competently and generate valid results, thereby promoting confidence in their testing results around the world. The standard facilitates cooperation between laboratories and other bodies by generating wider acceptance of test results among countries. Specifically, ISO/IEC 17025 enables the international acceptance of test reports and certificates without the need for further testing, which, in turn, facilitates international trade.

ISO/IEC 17025:2017(E) was developed to address market conditions and technology changes that have occurred since publication of the 2005 version of the standard. ISO has highlighted the reasons for the revised standard and the substantive changes included in the new version.<sup>1</sup> The changes include:

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<sup>1</sup> International Organization for Standardization – Brochure summarizes the key changes adopted in the 2017 version of ISO/IEC 17025. <https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf>

- A process approach that now matches that of newer standards such as ISO 9001 (quality management), and the ISO/IEC 17000 series (standards for conformity assessment activities), putting the emphasis on the results of a process instead of the detailed description of its tasks and steps.
- The standard has a stronger focus on information technologies. In recognition of the fact that hard-copy manuals, records and reports are slowly being phased out in favor of electronic versions, it incorporates the use of computer systems, electronic records and the production of electronic results and reports.
- A new section has been added introducing the concept of risk-based thinking and describes the commonalities with ISO 9001:2015, “Quality management systems – Requirements.”

The main sections in ISO/IEC 17025:2017(E) are:

- General Requirements that include a provision stating that the laboratory shall identify risks to its impartiality on an ongoing basis and demonstrate how it minimizes such risk.
- Structural requirements that cover provisions for defining the organization and management of the laboratory and the role and authorities for laboratory management.
- Resource requirements that address aspects of personnel, facilities, and equipment.
- Process requirements include evaluation of measurement uncertainty, validation of methods, handling of test items, and reporting of results.
- Management System Requirements that include control of system documents and records, actions to address risks and opportunities, corrective actions, internal audits, and management reviews.

## Transition Period from ISO/IEC 17025:2005(E) to ISO/IEC

### 17025:2017(E)

ILAC and ISO issued a “Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition.”<sup>2</sup>

The communiqué states:

Laboratories wishing to demonstrate their technical competence can do so via conformity with the international standard ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories.”

Conformity with this standard also means that the laboratory generally operates a management system in accordance with the principles of ISO 9001.

In 2017, ISO published a revision to ISO/IEC 17025 (previously published in 2005) to ensure that requirements continue to meet the demands of the modern market place. As a consequence, it has been agreed that laboratories that demonstrate conformity through third party accreditation will need to transition their processes to the new version within a defined timeframe. ILAC, in consultation with ISO, agreed that a three-year period from the date of publication shall be allowed for this transition.

During this transition period, it is important to note that both ISO/IEC 17025:2005E and ISO/IEC 17025:2017 are equally valid and applicable.

Formal accreditation to either standard granted by an accreditation body that is a signatory to the ILAC Arrangement should be recognized by the

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<sup>2</sup> <https://ilac.org/?ddownload=123170>.

market place, and it is strongly recommended that specifiers equally recognize both versions until after the 3-year transition period has closed.

In June 2020, because of the ongoing worldwide pandemic, ILAC and ISO issued a revision to the communiqué that states:

The end of the transition period has been extended from November 2020 to 1 June 2021. ILAC and ISO have agreed to this extension to ensure all laboratories are able to be transitioned following the restrictions imposed as a result of the global coronavirus disease 2019 (COVID-19) outbreak.

In January 2021, ILAC reported good progress towards achieving the revised June 2021 deadline, with 12 accreditation bodies confirming (as of November 30, 2020) that 100 percent of their laboratories accredited to ISO/IEC 17025 have transitioned to the 2017 version, and an additional 73 accreditation bodies confirming more than 75 percent laboratories had completed this transition.

#### *Scope and Purpose of ISO/IEC 17011*

ISO/IEC 17011 specifies requirements for the competence, consistent operation, and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies. For CPSC purposes, the conformity assessment bodies are third party testing laboratories.

As is the case for the ISO/IEC 17025 revision, the new version of ISO/IEC 17011 includes alignment with the common structure for the ISO 17000 series standards. The revised standard adds concepts of risk and risk-based assessments. The revised standard also incorporates competence criteria in the document, including an informative annex on knowledge and skills.

#### Transition Period from ISO/IEC 17011:2004(E) to ISO/IEC

17011:2017(E)



The transition from ISO/IEC 17011:2004(E) to ISO/IEC 17011:2017(E) was completed in December 2020. All ILAC-MRA signatory accreditation bodies are now conducting assessment activities according to ISO/IEC 17011:2017(E).

### **C. Description of the Direct Final Rule**

The direct final rule (DFR) only amends those sections of 16 CFR parts 1107 and 1112 that incorporate by reference or refer to ISO/IEC 17025:2005(E) and ISO/IEC 17011:2004(E). The DFR updates the incorporation by reference provisions of the regulations and references to the standards in 16 CFR parts 1107 and 1112 from ISO/IEC 17025:2005(E) and ISO/IEC 17011:2004(E) to ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E), as applicable, in the sections listed below:

#### *16 CFR part 1107*

- Section 1107.21(d)(1)
- Section 1107.21(g)
- Section 1107.26(a)(3)(iii)

#### *16 CFR part 1112*

- Section 1112.3 definition of Accreditation body
- Section 1112.13(a)(2)(i)
- Section 1112.13(i)
- Section 1112.43(a)(3)

The DFR makes no other changes to part 1107 or 1112.

### **D. Effective Date**

The Administrative Procedure Act (APA) generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1).

The DFR sets an effective date of 90 days after publication in the *Federal Register*.

CPSC staff determined that all testing laboratories that are currently CPSC-accepted, and

testing laboratories that are seeking CPSC-acceptance, will have completed their accreditation renewal to ISO/IEC 17025:2017(E) before the rule's effective date. Thus, the effective date for rule is [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

#### **E. Incorporation by Reference**

The DFR updates the sections of 16 CFR parts 1107 and 1112 that incorporate by reference ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E). The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B, of this preamble summarizes the major provisions of ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E) that the Commission incorporates by reference into sections of 16 CFR parts 1107 and 1112. The standard is reasonably available to interested parties and interested parties can purchase a copy of ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E) from the International Organization for Standardization (ISO), ISO Central Secretariat Chemin de Blandonnet 8 CP 401 - 1214 Vernier, Geneva, Switzerland; Telephone + 41 22 749 01 11, Fax + 41 22 733 34 30; <http://www.iso.org/iso/home.htm>. Interested parties can also schedule an appointment to inspect a copy of the standards at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: 301-504-7479; email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

#### **F. Direct Final Rule Process**

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551-559) generally requires agencies to

provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency, “for good cause finds,” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* 553(b)(B). The Commission concludes that when merely updating the incorporations by references contained in 16 CFR parts 1107 and 1112 to reflect the current versions of ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E), notice and comment is unnecessary.

The purpose of this direct final rule is to update the references in the CFR so that it reflects the versions of the voluntary standards currently in effect. The ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E) updates to the voluntary standards are not controversial, and are almost universally complied with by the testing and accreditation community involved in CPSA required testing. We do not expect any adverse comments regarding the updates to the references to ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E) in the CFR.

In Recommendation 95-4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the “unnecessary” prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. In accordance with ACUS’s recommendation, the Commission considers a significant adverse comment to be “one

where the commenter explains why the rule would be inappropriate,” including an assertion challenging “the rule’s underlying premise or approach,” or a claim that the rule “would be ineffective or unacceptable without change.” 60 FR 43108, 43111. As noted, this rule simply updates the references in the CFR to reflect noncontroversial changes to ISO/IEC 17025:2017(E) and ISO/IEC 17011:2017(E) and are almost universally complied with by the testing and accreditation community involved in CPSA required testing.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

#### **G. Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. 5 U.S.C. 603 and 604. As explained above, the Commission has determined that notice and comment is not necessary for this direct final rule. Thus, the RFA does not apply. We also note the limited nature of this document. The amendments to parts 1107 and 1112 simply update the incorporations by reference provisions and citations in the regulations to the current versions of ISO/IEC 17025 and ISO/IEC 17011 and will not result in any substantive changes to the regulations. Rather, with this action, the CFR will reflect the current versions of ISO/IEC 17025 and ISO/IEC 17011 in 16 CFR parts 1107 and 1112. However, the impact of the direct final rule on any testing laboratory that maintains its accreditation solely to conduct third party testing is not

expected to be large and would be undertaken by the testing laboratory only if it expected to make sufficient revenue from third party testing under the CPSA to justify the expense.

## **H. Environmental Considerations**

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

## **I. Congressional Review Act**

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a "major rule."

Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

## **List of Subjects**

### *16 CFR Part 1107*

Business and industry, Children, Consumer protection, Imports, Incorporation by reference, Product testing and certification, Records, Record retention, Toys.

### *16 CFR Part 1112*

Audit, Consumer protection, Incorporation by reference, Third party conformity assessment body requirements.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

## **PART 1107—TESTING AND LABELING PERTAINING TO PRODUCT CERTIFICATION**

1. The authority citation for part 1107 continues to read as follows:

**Authority:** 15 U.S.C. 2063, Sec. 3, 102 Pub. L. 110-314, 122 Stat. 3016, 3017, 3022.

2. Amend § 1107.21 by:

- a. In paragraph (d)(1), removing the phrases “ISO/IEC 17025:2005(E)” and “ISO/IEC 17011:2004(E)” everywhere they appear and adding in their places the phrases “ISO/IEC 17025” and “ISO/IEC 17011”, respectively; and
- b. Revising paragraph (g).

The revision reads as follows:

### **§ 1107.21 Periodic testing.**

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(g) *Incorporation by reference.* The Director of the Federal Register approves the incorporation by reference of the standards in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov), or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

(1) International Organization for Standardization (ISO), ISO Central Secretariat  
Chemin de Blandonnet 8 CP 401 - 1214 Vernier, Geneva, Switzerland; Telephone + 41  
22 749 01 11, Fax + 41 22 733 34 30; <http://www.iso.org/iso/home.htm>.

(i) ISO/IEC 17011:2017(E) (ISO/IEC 17011), “Conformity assessment - Requirements  
for accreditation bodies accrediting conformity assessment bodies,” November 10, 2017;  
and

(ii) ISO/IEC 17025:2017(E) (ISO/IEC 17025), “General requirements for the competence  
of testing and calibration laboratories,” November 10, 2017.

(2) [Reserved]

#### **§ 1107.26 [Amended]**

3. In § 1107.26(a)(3)(iii), remove the phrase “ISO/IEC 17025:2005(E)” and add in its  
place the phrase “ISO/IEC 17025 (see § 1107.21 for availability)”.

### **PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY**

#### **CONFORMITY ASSESSMENT BODIES**

4. The authority citation for part 1112 is continues to read as follows:

**Authority:** Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

#### **§ 1112.3 [Amended]**

5. In § 1112.3, in paragraph (1) under the definition for “Accreditation body”, remove the  
phrase “ISO/IEC 17025:2005” and add in its place the phrase “ISO/IEC 17025 (see §  
1107.21 of this chapter for availability)”.

6. Amend § 1112.13 by:

a. In paragraph (a)(2)(i)(A), removing the phrase “ISO/IEC Standard 17025:2005(E)” and  
adding in its place the phrase “ISO/IEC 17025”; and

b. Revising paragraph (i).

The revision reads as follows:

**§ 1112.13 How does a third party conformity assessment body apply for CPSC acceptance?**

\* \* \* \* \*

(i) *Incorporation by reference.* The Director of the Federal Register approves the incorporation by reference in paragraph (a)(2)(i) of this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of ISO/IEC 17025:2017(E), “Requirements for the competence of testing and calibration laboratories,” approved November 10, 2021 from the International Organization for Standardization (ISO), ISO Central Secretariat Chemin de Blandonnet 8 CP 401 - 1214 Vernier, Geneva, Switzerland; Telephone + 41 22 749 01 11, Fax + 41 22 733 34 30; <http://www.iso.org/iso/home.htm>. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov), or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

**§ 1112.43 [Amended]**

7. In § 1112.43(a)(3), remove the phrase “ISO/IEC 17025:2005(E)” and add in its place the phrase “ISO/IEC 17025:2017(E)”.

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Alberta E. Mills, Secretary,

U.S. Consumer Product Safety Commission.